MAY - 9 2012

K120353

510(k) Summary

The following 510(k) summary is submitted as required by 21 CFR Part 807.92:

Date Prepared: February 01, 2012

1. **Submission information:**

a) Submitter

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b) U.S Agent

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Contact	Priscilla Chung (juhee.c@lkconsultinggroup.com)

2. **Device Identification:**

Trade Name: SYNSTER® Pedicle Screw System

SYNSTER® PLUS Pedicle Screw System

Common Name: Pedicle Screw Spinal Fixation System

Classification Name: orthosis, spondylolisthesis spinal fixation
(21 CFR 880.3070, Product Code MNH)

orthosis, spinal pedicle fixation
(21 CFR 880.3070, Product Code MNI)

3. **Identification of the Legally Marketed Devices (Predicate):**
Substantial Equivalence for the SYNSTER® Pedicle Screw System and SYNSTER® PLUS Pedicle Screw System is based on its similarities in indications for use, design features, operational principle and material composition when compared to the predicate devices cleared under the follows:

Tyche® Pedicle Screw System (K100373)
OPTIMA™ Spinal System (K024096)
VERTEBRON PSS™ Pedicle Screw System (K043152)

4. **Device Description:**
The SYNSTER® Pedicle Screw System and the SYNSTER® PLUS Pedicle Screw System are posterior, noncervical, pedicle screw spinal system which consists of a variety of shapes and sizes of rods, screws, and cross links which can be rigidly locked into a variety of configurations, made for the individual case. Please note that certain components are specifically designed to connect to ø 5.5mm or ø 6.0mm rods. Care should be taken so that the correct components are used in the spinal construct. The Pedicle Screw Spinal Fixation System was made out of medical grade titanium alloy described by standard such as ASTM F136. **Never use stainless steel and titanium implant components in the same construct.**
To achieve best results, do not use any of the Pedicle Screw Spinal Fixation System with components from any other system or manufacturer unless specifically allowed to do so in this. The Pedicle Screw Spinal Fixation System implant will be provided non-sterile.

5. **Indications for Use:**
The SYNSTER® Pedicle Screw System and the SYNSTER® PLUS Pedicle Screw System are non-cervical, pedicle screw systems indicated for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-S 1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

   In addition, the SYNSTER® Pedicle Screw System and the SYNSTER® PLUS Pedicle Screw System are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis)

6. **Summary of Technology Characteristics:**
The SYNSTER® Pedicle Screw System and the SYNSTER® PLUS Pedicle Screw System are substantially equivalent to the above listed predicate devices in terms of materials, design, indications for use and operational principles. Based on the provided information in this premarket notification, it can be concluded that the subject device is substantial equivalent to the predicate devices and is safe and effective when used as intended.

7. **Discussion of Non-clinical Testing**
The follow non-clinical tests were conducted:
   - Static and dynamic compression testing, conducted in accordance with ASTM F1717
   - Static tension testing in accordance with ASTM F1717
   - Static torsion testing, conducted in accordance with ASTM F1717

8. **Conclusions**
The subject and predicate device(s) share the same intended use, design features and material. The data of tests performed according to ASTM F1717 indicate that The SYNSTER® Pedicle Screw System and the SYNSTER® PLUS Pedicle Screw System

meet required mechanical strengths based on the predicate comparison. Some of the predicate devices have an insignificantly different geometry than The SYNSTER® Pedicle Screw System and the SYNSTER® PLUS Pedicle Screw System. But the non-clinical mechanical test results demonstrate that the minor differences do not impact performance as compared to the predicates and demonstrate that the SYNSTER® Pedicle Screw System and the SYNSTER® PLUS Pedicle Screw System are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Re: K120353
Trade/Device Name: SYNSTER® Pedicle Screw System
SYNSTER® PLUS Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: April 6, 2012
Received: April 12, 2012

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Peter D Rumm MD

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120353

Indications for Use

510(k) Number (if known): K120353

Device Name: SYNSTER® Pedicle Screw System
SYNSTER® PLUS Pedicle Screw System

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Prescription Use__X__ (Part 21CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120353